UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/893,080	12/19/1997	ALAN M. WARSHAWSKY		7559

46137 7590 09/30/2004

SYNNESTVEDT & LECHNER LLP
2600 ARAMARK TOWER
1101 MARKET STREET
PHILADELPHIA, PA 19107-2950

EXAMINER	
KIFLE, BRUCK	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/893,080	WARSHAWSKY ET AL.	
	Examiner	Art Unit	
	Bruck Kifle, Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and remarks filed 08/04/04 have been received and reviewed. Claims 1-47 are still pending in this application.

Claim Rejections - 35 USC § 112

Claims 1-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The group defined as "C_3-C_9 heteroaryl" is indefinite. Applicants point to page 9, lines 23 to 26 for support of this group.

These lines state "The term "C_3-C_9 heteroaryl" means a cyclic or bicyclic, aromatic assemblage of conjugated carbon atoms and from 1 to 3 nitrogen, oxygen and sulfur atoms, for example, pyridinyl, 2-quinoxalinyl, quinolinyl, pyridazine, pyrimidyl, pyrazolyl, pyrazyl, thiophyl, furyl, imidazolyl, oxazolyl, thiazolyl and the like."

This definition is flawed. The term "heteroaryl" should be defined by how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present. In the instant case, the number and kind of atoms intended is not clear. What, for example, is a C_3 heteroaryl? A definition in the specification which distorts the meaning of an accepted term renders the claims confusing (In re Hill 73 USPQ 482). Applicant's definition in the specification is inconsistent because it limits heteroaryl to having only carbon atoms.

The U.S. Court of claims held to this standard in Lockheed Aircraft vs. Unites States, 193 USPQ 449, "claims measure the invention and resolution of invention must be based on what is claimed."

The CCPA said "that invention is the subject matter defined by the claims submitted by the applicant." "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim" (In re Priest, 199 USPQ 11 at 15).

Therefore, Applicants need to indicate, in the claim, what is intended.

Claims 36, 37, 41, 42 and 46 are again rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating the diseases embraced by these claims. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference. Applicant's arguments have been fully considered but not found persuasive.

In evaluating the enablement question, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The Examiner has considered each factor.

See for example, the Greenwald chapter in Annals of the New York Academy of Sciences *878:413-419 (1999).* The title is "Thirty-six Years in the Clinic without an MMP Inhibitor: What Hath Collagenase Wrought?" Therein is cited that "Designing human trials to demonstrate MMP inhibition and clinical efficacy is a daunting problem," indicating the difficulty of making MMP inhibitors to work.

The how to use portion of the statute has not been addressed. This means that Applicants must teach the skilled practitioner, in this case a physician, how to treat a given subject. The physician clearly must know what disease and what symptoms is to be treated. In a case concerning the patentability of compounds with "good effects against a wide range of insects" *In re LORENZ AND WEGLER*, 134 USPQ 312 U.S. Court of Customs and Patent Appeals upheld the rejection of compound claims, noting that "[a]ppellants are seeking a seventeen year monopoly. We would remind them that if they have in truth invented something which promotes the progress of science and the useful arts, then in exchange for a patent grant they must make a full and complete disclosure of their invention, leaving nothing to speculation or doubt. That Congress so intended is evident from the strong and comprehensive language of Section 112 which appellants here have failed to satisfy." In this case, Applicants have not provided what is being treated by claim 36, who the subject is, how one can identify said subject (i.e. how one can identify a subject in need), given no specific dose, given no specific dosing regimen, given no specific route of administration, and do not specify what diseases or symptom they intend to treat.

As the Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general

as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
September 28, 2004